

**MEDICATION GUIDE**  
**DEXILANT (decks-ĭ-launt)**  
**(dexlansoprazole)**  
**delayed-release capsules**

Read this Medication Guide before you start taking DEXILANT and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

**What is the most important information that I should know about DEXILANT?**

**DEXILANT may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.**

**DEXILANT can cause serious side effects, including:**

- **Diarrhea.** DEXILANT may increase your risk of getting severe diarrhea. This diarrhea may be caused by an infection (*Clostridium difficile*) in your intestines.  
Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.
- **Bone fractures.** People who take multiple daily doses of proton pump inhibitor medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. You should take DEXILANT exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take DEXILANT.

DEXILANT can have other serious side effects. See “**What are the possible side effects of DEXILANT?**”

**What is DEXILANT?**

DEXILANT is a prescription medicine called a proton pump inhibitor (PPI). DEXILANT reduces the amount of acid in your stomach.

DEXILANT is used in adults:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE).
- for up to 6 months to continue healing of erosive esophagitis and relief of heartburn.
- for 4 weeks to treat heartburn related to gastroesophageal reflux disease (GERD).

GERD happens when acid from your stomach enters the tube (esophagus) that connects your mouth to your stomach. This may cause a burning feeling in your chest or throat, sour taste or burping.

It is not known if DEXILANT is safe and effective in children under 18 years of age.

**Who should not take DEXILANT?**

Do not take DEXILANT if you are allergic to dexlansoprazole or any of the other ingredients in DEXILANT. See the end of this Medication Guide for a complete list of ingredients in DEXILANT.

**What should I tell my doctor before taking DEXILANT?**

**Before you take DEXILANT, tell your doctor if you:**

- have been told that you have low magnesium levels in your blood
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if DEXILANT will harm your unborn baby.
- are breastfeeding or planning to breastfeed. It is not known if DEXILANT passes into your breast milk.

You and your doctor should decide if you will take DEXILANT or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take DEXILANT.

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. DEXILANT may affect how other medicines work, and other medicines may affect how DEXILANT works.

Especially tell your doctor if you take:

- an antibiotic that contains ampicillin
- atazanavir (Reyataz)
- digoxin (Lanoxin)
- a product that contains iron
- ketoconazole (Nizoral)
- warfarin (Coumadin, Jantoven)
- tacrolimus (Prograf)
- methotrexate

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

### **How should I take DEXILANT?**

- Take DEXILANT exactly as prescribed by your doctor.
- Do not change your dose or stop taking DEXILANT without talking to your doctor first.
- You can take DEXILANT with or without food.
- Swallow DEXILANT capsules whole.
- If you have trouble swallowing DEXILANT capsules whole, you can open the capsules and sprinkle the contents on a tablespoon of applesauce. Be sure to swallow the applesauce mixture right away. Do not chew the mixture. Do not store the mixture for later use.
- If you take too much DEXILANT, call your doctor right away or go to the nearest hospital or emergency room.

### **What are the possible side effects of DEXILANT?**

**DEXILANT may cause serious side effects, including:**

- **See “What is the most important information I should know about DEXILANT?”**
- **Low magnesium levels in your body.** This problem can be serious. Low magnesium can happen in some people who take a proton pump inhibitor medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium.

Tell your doctor right away if you develop any of these symptoms:

- seizures
- dizziness
- abnormal or fast heartbeat
- jitteriness
- jerking movements or shaking (tremors)
- muscle weakness
- spasms of the hands and feet
- cramps or muscle aches
- spasm of the voice box

Your doctor may check the level of magnesium in your body before you start taking DEXILANT, or during treatment, if you will be taking DEXILANT for a long period of time.

The most common side effects of DEXILANT include:

- diarrhea
- stomach pain
- nausea
- common cold
- vomiting
- gas

Other side effects

- **Serious allergic reactions.** Tell your doctor if you get any of the following symptoms with DEXILANT:
  - rash
  - face swelling
  - throat tightness
  - difficulty breathing

Your doctor may stop DEXILANT if these symptoms happen.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DEXILANT. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **How should I store DEXILANT?**

- Store DEXILANT at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep DEXILANT and all medicines out of the reach of children.**

### **General information about DEXILANT**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DEXILANT for a condition for which it was not prescribed. Do not give DEXILANT to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about DEXILANT. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DEXILANT that is written for healthcare professionals.

For more information, go to [www.DEXILANT.com](http://www.DEXILANT.com) or call 1-877-825-3327.

### **What are the ingredients in DEXILANT?**

Active ingredient: dexlansoprazole.

Inactive ingredients: sugar spheres, magnesium carbonate, sucrose, low-substituted hydroxypropyl cellulose, titanium dioxide, hydroxypropyl cellulose, hypromellose 2910, talc, methacrylic acid copolymers, polyethylene glycol 8000, triethyl citrate, polysorbate 80, and colloidal silicon dioxide. The capsule shell is made of hypromellose, carrageenan and potassium chloride. Based on the capsule shell color, blue contains FD&C Blue No. 2 aluminum lake; gray contains black ferric oxide; and both contain titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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